

**ISSUE BRIEF**

**Value Assessment in the Context of COVID-19**

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**POLICY QUESTION**

How should value assessment methods adapt scientifically in light of the rapidly evolving health and economic challenges highlighted by the COVID pandemic?

**KEY TAKEAWAYS**

- Efforts to rapidly respond to the current novel coronavirus pandemic have highlighted the need for credible, relevant, and timely information on the value of available options for treatment and prevention efforts.
- The urgent need for insights into the value of COVID responses highlights important advances needed in the methods used for quantitative value assessment.
- In particular, COVID-related value assessments must better account for scientific uncertainty, incorporate broader societal perspectives and impacts on the macroeconomy, and support decisions that increase equity and reduce health disparities.
- Vigorous research and collaboration among diverse stakeholders are needed to advance these methods, test emerging approaches, and ultimately better align value assessments with decision-makers' needs.

**ASSESSING VALUE IN THE COVID CONTEXT**

The COVID\* pandemic has caused unprecedented mortality globally and continues to threaten our health and economy. As we observe daily statistics about spread and

reports of rapid evidence development for diagnostics, treatments, and vaccines, it is natural that vigorous debate emerges over the benefit, costs, and risks—in other words, the value—of bringing such technologies to market.

Objective information on the relative value of prevention and treatment strategies can help health care decision-makers allocate resources more effectively and efficiently. New health technologies can bring a wide range of benefits, including reduced morbidity and mortality, improved quality of life, and increased economic productivity, but they can also significantly affect health care costs. In a world of rising overall health care spending and constrained resources, accurate estimates of the value of new technologies compared to one another and to established standards of care can inform difficult decisions about how to allocate scarce resources. These estimates are generated through economic value assessment (VA), most frequently using cost-effectiveness analysis.

The Institute for Clinical and Economic Review (ICER) earlier this year published its first cost-effectiveness analysis for remdesivir, the first drug approved to treat COVID. While some policy analysts took issue with the premature timing and specific methodologies used, the analysis and subsequent developments have elevated important discussions about the methods and inputs used to assess the value of future therapeutic interventions.<sup>1,2</sup>

With other diagnostics, treatments, and vaccines likely on the horizon, the pandemic has highlighted a series of complex issues in how we define and assess value for promising health interventions. While these challenges are mostly not exclusive to the pandemic or new to the VA community, the pandemic has provided us with a unique context and the urgency to address them. So, what can this pandemic teach us about where VA methodologies should be headed, and what are the gaps in our existing methodology inventory?

\*For simplification and readability, we use “COVID” throughout to refer to both the novel coronavirus causing the current pandemic and the disease (COVID-19) that it causes.

## ACCOUNTING FOR UNCERTAINTY

Our knowledge and evidence base about COVID are evolving daily. Urgently needed responses to the pandemic must confront – and account for – high degrees of scientific uncertainty. Such uncertainty also poses unique challenges for VA efforts aiming to support decision-making in this context.

### Grappling with Uncertainty

Uncertainty surrounds many of the elements required to conduct COVID-related value assessments, and there is also uncertainty surrounding other variables related to the pandemic response. These variables are highlighted below.



1

#### Disease Characteristics

Our understanding of the novel virus's pathology, pathogenesis, prevalence, risk factors, and long-term health impacts is limited and rapidly evolving.



2

#### Effectiveness and Risks of Novel Interventions

Given the urgent need for therapies and vaccines, novel health interventions are more likely to be approved and adopted based on preliminary short-term clinical evidence, which comes with great uncertainty.



3

#### Societal Impacts

The novel coronavirus affects not only those who are infected but society at large, yet it remains unknown exactly how and to what extent the pandemic and related public health measures will impact society, e.g., in terms of the long-term education and health outcomes of the general population.

To estimate the relative value of intervention compared to its alternatives, value assessments bring together scientific evidence in a model (e.g., a set of mathematical equations) designed to predict, as best as possible, the long-term expected benefits and costs of the intervention in the real world. Uncertainty exists in any VA model, but the challenges and potential impacts on results are particularly acute in the COVID context. It is essential that VA explicitly account for uncertainty by incorporating flexibility in modeling approaches (e.g., model structure, inputs), thoroughly examining the sensitivity of the results based on existing evidence, and adapting to new evidence in a timely fashion.

While testing models for sensitivity to inputs is common practice, understanding the implications of modeling assumptions is arguably equally important but seldom practiced. Prior research using the open-source IVI-RA model illustrates how different structural assumptions can lead to drastically varying cost-effectiveness estimates.<sup>3,4</sup>

## CONSIDERING BROADER PERSPECTIVES

Therapies to treat or prevent COVID infection affect not only health outcomes, but also the functioning and well-being of society at large. While these broader effects are an important component of assessing value in health care more broadly, the COVID pandemic particularly highlights the following important elements.

### Novel Value Elements in the Health Care Sector Perspective

Given the far-reaching social impacts of COVID, it is imperative that value assessment models consider and prioritize the broader societal perspective (as compared to a more limited health system perspective, for example). In 2018, ISPOR's Special Task Force on Value Assessment Frameworks published recommendations for vigorous research and testing to incorporate "novel elements of value" into models.<sup>5</sup> These novel elements of value include value factors in the societal perspective that are highly meaningful in the pandemic context, which include fear of contagion, severity of illness, insurance value, and innovation and its spillover effects. While not commonly assessed in existing VA efforts, these novel value elements should be included to allow decision-makers to more comprehensively assess the value of novel technologies.

### Account for Heterogeneity

Patients vary in terms of their clinical and sociodemographic characteristics, responses to treatment, and care-related preferences, and this heterogeneity often has important implications for VA. In the context of the COVID pandemic, where decisions about policy and resource allocation affect the population as a whole, accounting for this heterogeneity in VA may be especially important. Populations vary, for example, in their perception of attitudes toward risk of infection and their willingness to trade this risk off against lifting of mask requirements or social distancing measures.<sup>6</sup> Attitudes toward the risk of new therapies also vary, a key example being (historically justified) skepticism about medicine and physicians in Black communities.<sup>7,8</sup>

These heterogeneous preferences directly affect how individuals make difficult trade-offs during the COVID era. The recently-proposed GRACE framework is a promising potential approach to account for these risk-related preferences by unifying heterogeneous risk preferences, disease severity, and other novel value elements.<sup>9</sup>

## Public Health Interventions and Policies

While traditional VA focuses on therapeutic interventions as comparators, VA models for COVID should also include public health interventions such as social distancing and mask-wearing. Due to the prevalence of COVID and high risk of infection, public health policies play an essential role and could prove to be more cost-effective at a population level. Some recent research has shown preliminary evidence that social distancing measures, along with effective testing and contact tracing, could help minimize the burden of COVID on the public health system.<sup>10</sup> Such evidence provides necessary inputs to incorporate policy interventions into VA models.

## Negative Spillover Effects on Non-COVID Health Care

The rapid arrival of the COVID pandemic directly impacted both the availability and use of health care in general.<sup>11</sup> Many services became unavailable due to the redirection of resources to COVID care (conversion of hospital wings to COVID-ready ICU beds, for example, and demands on providers caring for COVID patients) and reduction in appointments and clinic closures due to risks of transmission. As a result, delays in receiving non-urgent procedures, tests, and in-person visits may lead to poorer health outcomes and delayed diagnoses. Similarly, care is also delayed as individuals with non-COVID concerns – including those experiencing cardiac emergencies – have chosen not to seek care because of fear of infection.<sup>12</sup>

These changes have immediate implications for outcomes, especially where care for urgent health issues has been delayed.<sup>12</sup> The COVID pandemic is also likely to have long-term consequences for both the health system and the health of the population, though, especially due to financial strain on health systems and delays in diagnosing and treating chronic diseases. The extent to which COVID-focused interventions impact these spillover effects – by reducing risk of transmissions, for example, or shortening time spent in an ICU – is an important component in assessing relative value.

## Building Cross-Sector Linkages for the Aggregate Macroeconomy

Structurally, VA models should also seek to establish the linkages of the health care sectors to other sectors in the broader aggregate macroeconomy.<sup>13</sup> Traditional cost-effectiveness models typically focus on health-associated outcomes and rarely model the cross-sector interactions.

Pandemic-related impacts on production and supply chains, alongside reduced consumer activity, have caused large scale spikes in unemployment and halted global economic growth. VA methods need to take into account the impacts of novel health interventions on economic activities, including consumption, investments, and employment. While less commonly used in the existing VA studies, several modeling frameworks (e.g., the computable general equilibrium) offer promising solutions to estimate the impacts of novel health interventions on the broader economy.<sup>14,15</sup>

## INFORMING AND FACILITATING DECISION-MAKING

The issues described above are essential to accurately assessing the value of interventions in the context of the pandemic, but arriving at these estimates is only the first step. Value assessments are only meaningful insofar as they support more efficient and beneficial decisions about resource allocation. The current pandemic highlights more important issues that must be grappled with in decision-making around the use of health care resources – not only related to COVID but in health care more broadly.

## Multi-party Coordination and Deliberative Processes

In a decentralized health care system like that of the United States, stakeholders with different interests and priorities must work together to arrive at decisions that affect all. For this to be possible, alternatives to cost-effectiveness-based decision-analysis may be needed to facilitate multi-stakeholder joint decision-making. For example, multi-criteria decision analysis (MCDA) is an alternative approach that could capture a broader set of value elements than traditional cost-effectiveness analysis and is more suited to enable multiple stakeholders to build consensus based on how different sets of decision criteria are prioritized.<sup>16,17</sup>

## Inequity

Addressing the issues of equity and disparities in care is also a critical element in the decision equation for COVID. The pandemic has disproportionately impacted minority populations—Black populations in particular—in terms of incidence, prevalence, and outcomes.<sup>18,19</sup> Racial/ethnic minority and socioeconomically disadvantaged populations are less likely to have access to health insurance and quality health services. These individuals are also at higher risk of losing their income, as they work in industries particularly vulnerable to COVID. Given the differential impacts of the pandemic on subpopulations, it is crucial to ensure equity—

in terms of access, financial burden, and outcomes—as a key objective in value assessment and subsequent decision-making. Efforts should be made to ensure that minority populations are represented in the data collection (e.g., in clinical trials) and decision-making process.

Equity impact and equity trade-off analysis (e.g., distributional cost-effectiveness analysis) are established methodologies for balancing inequity reduction versus overall potential gain in efficiency by the selection of the most cost-effective treatments at a population level.<sup>20,21</sup>

## CONCLUSION

The COVID pandemic has brought the importance of science-based decision-making to the fore, including the need for rigorous and accurate information to direct resources to the most valuable available treatments and interventions. How “value” is measured and translated into access, delivery, and payment policy has long-term consequences on both our health and well-being and on the future of investments in health care interventions. Importantly, many of the related issues we see in COVID-related value assessment apply to value assessment writ large. The COVID pandemic underscores the need for both rigorous research to advanced methods for value assessment and greater consensus on how clearer understandings of value can support decisions that provide the greatest benefit for all.

## ABOUT THE INNOVATION AND VALUE INITIATIVE

IVI is a 501(c)(3) nonprofit research organization committed to advancing the science, practice, and use of value assessment in health care to make it more meaningful to those who receive, provide, and pay for care through collaboration among thought leaders in academia, patient organizations, payers, life science firms, providers, delivery systems and other organizations.

### Authors:

Mark Linthicum, MPP  
Director of Scientific Communications  
Innovation and Value Initiative

Lou Garrison, PhD  
Professor Emeritus  
University of Washington  
School of Pharmacy

Richard Xie, PhD  
HEOR Research Manager  
Innovation and Value Initiative

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